



# STARCH 1500<sup>®</sup>

PARTIALLY PREGELATINIZED MAIZE STARCH

*Flexibility for performance*

# STARCH 1500® PARTIALLY PREGELATINIZED MAIZE STARCH

THE SUPERIOR MULTIFUNCTIONAL EXCIPIENT FOR  
SOLID DOSAGE DEVELOPMENT

*Starch 1500 is a unique pharmaceutical excipient combining several properties in a single product. Only Starch 1500 performs the multiple functions of a binder, disintegrant, flow-aid and self-lubricant. It is extremely versatile, being effective in a variety of processing methods for solid oral dosage forms. Starch 1500 also exhibits synergy, enhancing the functionality of other commonly used excipients in formulations.*

## MULTIFUNCTIONAL

Provides a unique range of functions:

- Binder
- Disintegrant
- Flow-Aid
- Lubricant

## VERSATILE

Flexible performance in a variety of applications:

	DIRECT COMPACTION	WET GRANULATION	CAPSULE PLUG FORMATION
Binder	X	X	X
Disintegrant	X	X	X
Flow-Aid	X	X*	X
Lubricant	X	X*	X

\* In the extra granular phase

## COST-EFFECTIVE

Cuts process and material costs by reducing or eliminating:

- Excess binders
- Superdisintegrants
- Additional lubricants and glidants
- Manufacturing steps

## MANUFACTURED FOR THE PHARMACEUTICAL INDUSTRY

- Manufactured in modern cGMP facilities dedicated solely to the production of pharmaceutical excipients

## INDUSTRY LEADING TECHNICAL EXPERTISE

- Worldwide manufacturing, distribution and technical service facilities
- Formulation and application development support
- Global regulatory assistance
- Innovative new product development

## DIRECT COMPACTION

Starch 1500 performs key functions in direct compaction formulations as a binder, disintegrant, flow-aid and self-lubricant. It also promotes formulation flexibility by complementing and enhancing the functionality of other excipients.

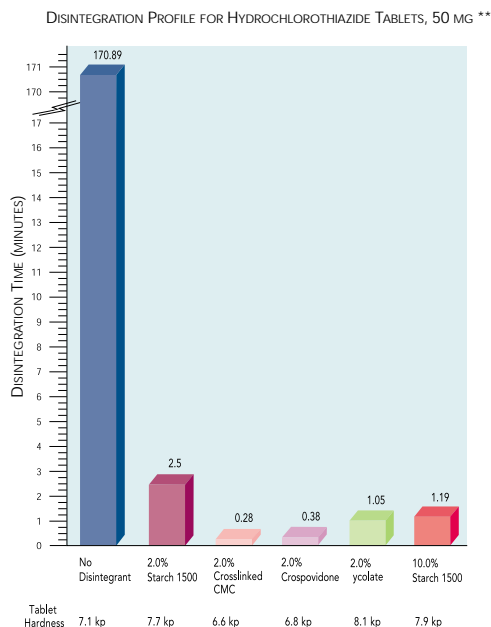
### BINDER

As a dry binder, it compresses well, predominately deforming plastically. Starch 1500 can be used with other excipients, such as microcrystalline cellulose, lactose, and dicalcium phosphate, to produce tablets with excellent hardness and low friability at compaction forces typically used in tableting operations.

### DISINTEGRANT

Starch 1500 performs the actions of two disintegrants; maize starch and free amylose in dry processes. In some applications, 2% to 10% of Starch 1500 provides disintegrant action as effective as super disintegrants, greatly reducing costs. (See Figure 1)

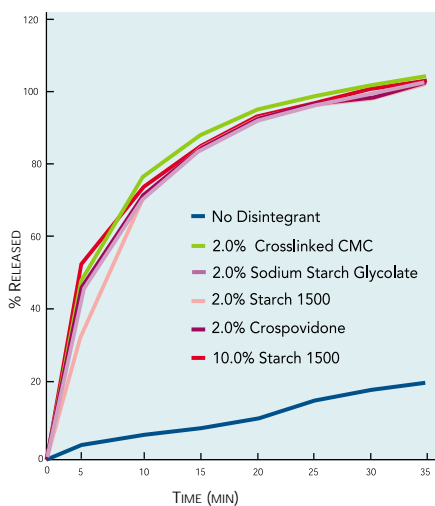
Figure 1



The combination of maize starch and free amylose has a positive impact on drug dissolution. Supporting the tablet disintegration data in Figure 1, the resulting drug dissolution data in Figure 2 compares Starch 1500 with more costly disintegrants.

**Figure 2**

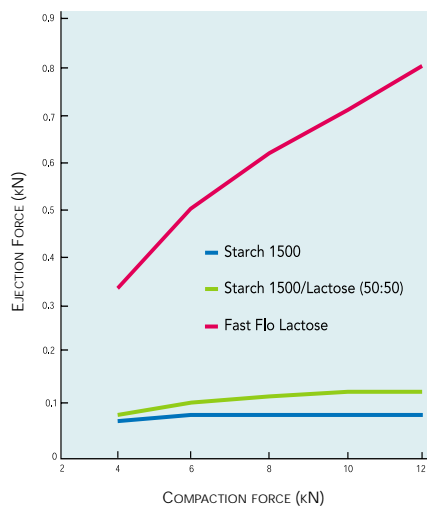
DISSOLUTION PROFILE FOR HYDROCHLOROTHIAZIDE TABLETS, 50 MG\*\*



\*\* Tablets were formulated with 25% hydrochlorothiazide, 0.25% magnesium stearate, and equal parts lactose and dicalcium phosphate. Equal portions of the lactose and dicalcium phosphate were substituted with 2% or 10% Starch 1500.

**Figure 3**

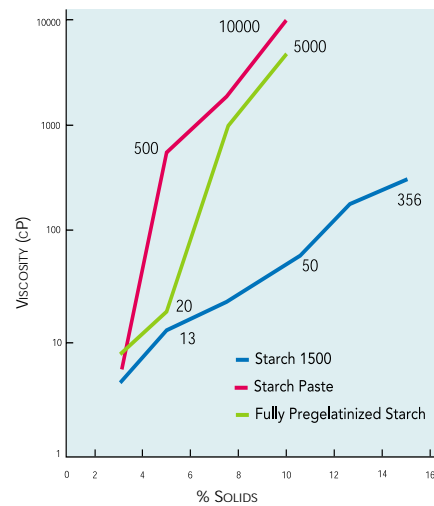
EJECTION FORCE VALUES FOR HYDROCHLOROTHIAZIDE TABLETS



Hydrochlorothiazide 25%, excipient 74.75%, 0.25% magnesium stearate as lubricant

**Figure 4**

CONCENTRATION DEPENDENT VISCOSITY PROFILES



Traditional starch paste at 85°C compared to Starch 1500 and a fully pregelatinized starch prepared in cold water

## FLOW-AID

Starch 1500 provides excellent flow properties, demanded by today's high-speed tableting and capsule filling equipment; ensuring that manufacturers can produce tablets and capsules with consistent uniform weight and drug content.

## SELF LUBRICANT

The high inherent lubricity of Starch 1500 enables the formulator to lower the levels of traditional lubricants, such as magnesium stearate. For example, magnesium stearate added in high levels, or when over-blended, can slow dissolution and cause problems with compaction (soft tablets) and film coating (poor film adhesion). Therefore, Starch 1500 enables lubricant levels and their potential problems to be reduced or eliminated. (See Figure 3)

## WET GRANULATION

In wet granulation applications, Starch 1500 exhibits dual functionality as both binder and disintegrant as a result of partial cold water solubility. Starch 1500 allows process flexibility: it can be dry-blended with other ingredients before adding water, or a portion can be dispersed in cold water. A slurry of Starch 1500 in cold water provides effective binding properties at higher solids and lower viscosity than traditional starch pastes, which must be heated and prepared at lower concentrations. (See Figure 4) Processing costs are reduced by eliminating the time and expense of preparing traditional binder solutions. In addition, granulations using Starch 1500 as a binder give excellent tablet hardness and fast disintegration.

In fluid bed granulations, Starch 1500 alone can be used as both binder and disintegrant. For example, capsule-shaped acetaminophen tablets, 500mg, of excellent hardness and friability values of less than 0.19% were produced through the simple formulation of 85% acetaminophen and 15% Starch 1500 used as the wet granulation binder. In this formulation, Starch 1500 functioned as an exceptional disintegrant with disintegration time less than 1 minute. Dissolution was excellent. Test results showed 80% drug release within 5 minutes. In addition, the low viscosity of Starch 1500 in cold water allowed higher binder content solutions and faster spray times, resulting in reduced process times.

## CAPSULE PLUG FORMATION

Starch 1500, as a flow-aid, improves uniformity of capsule fill. As a binder, Starch 1500 facilitates plug formation in dosator-type equipment and reduces powder fallout when the plug is transferred. The inherent lubricity of Starch 1500 means a lower force to eject material into the capsule shell (compared to other excipients) and leads to reduced wear on dosator-type equipment.

## STARCH 1500 PRODUCT RANGE

Colorcon has made Starch 1500 even more versatile by developing a line of products for optimal performance applicable to a variety of formulations. The Starch 1500 product range is produced exclusively for the pharmaceutical industry under cGMP guidelines. Starch 1500 products are designed to meet regulatory needs worldwide. Specific products conform to the USP/NE, Ph.Eur, and JPE compendial monographs.



# C O L O R C O N

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## S U P P L I E R O F C H O I C E

Colorcon has a firm commitment to providing products and services for high quality coating systems and formulated products along with technical support dedicated to meeting customers' needs. In addition, a focus on market issues and technology development has earned Colorcon an international reputation in the pharmaceutical industry as the supplier of choice.

Colorcon's worldwide network of technical service laboratories and experts bring solutions to our customers when and where they are needed. These resources serve all aspects of customer projects including; formulation development, application development, scale-up support and regulatory information. We understand the impact of speed to market in the competitive fast paced pharmaceutical industry and support our customers in the production of highly effective formulations in reduced time frames.

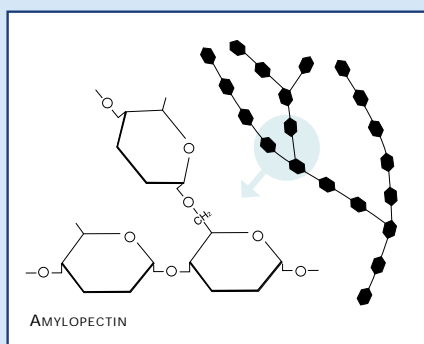
*Take advantage of our experience, technology and creativity; enhance your position in the marketplace.*

*Make Colorcon your partner, your supplier of choice.*

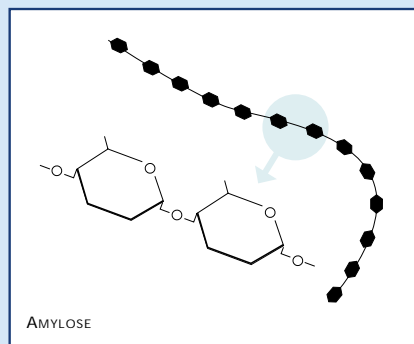
## UNIQUE MANUFACTURING PROCESS

Starch 1500 is a partially pregelatinized maize starch manufactured exclusively for the pharmaceutical industry in dedicated cGMP facilities. The process involves a physical modification of the starch (no chemical additives or surfactants are used), resulting in the combined benefits of the soluble and insoluble functionality of Starch 1500.

Maize starch is composed of two polymers, amylose and amylopectin which are tightly bound in a specific spherocrystalline structure. Through partial pregelatinization, the bond between a portion of the two polymers is broken, providing Starch 1500 with its unique properties. The process results in partial solubility, increased particle size, improved flow properties and compactability.



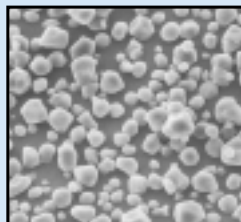
Amylopectin has a branched-chain molecular structure, which makes it readily soluble in cold water. Amylopectin functions as a binder in wet granulation processes.



Amylose has a straight-chain molecular structure, which exhibits a very strong intermolecular bonding capability. Amylose swells significantly when wetted, giving it excellent disintegrating characteristics.

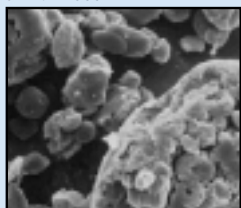
## ONE EXCIPIENT, MULTIPLE FUNCTIONS

STARCH NF



Colorcon's unique manufacturing process results in the most effective functional balance for Starch 1500, providing good cold water binding and granulation properties, yet retaining effective tablet disintegrant properties. The physical structure of Starch 1500 also imparts good compactability, flow and lubrication capabilities.

STARCH 1500\*



These multifunctional properties can be utilized in a variety of applications, including direct compaction, wet granulation, fluid bed granulation and capsule plug formation. The distinct benefits of Starch 1500 can bring significant process flexibility to solid dosage forms.

SEM photo of Starch 1500 shows individual starch grains along with aggregates bonded to the hydrolyzed starch. Starch 1500 has better flow characteristics than Starch NF and has much higher compactability. Photos shown at 10 microns.

# STARCH 1500®

PARTIALLY PREGELATINIZED MAIZE STARCH

- Multifunctional for formulation versatility
- Flexibility for performance in a variety of applications
- Manufactured exclusively for the pharmaceutical industry
- Meets global regulatory requirements

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## WORLD HEADQUARTERS

### COLORCON

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<i>UNITED STATES</i>		
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Indianapolis, Indiana	317-545-6211	317-545-6218
Humacao, Puerto Rico	787-852-3815	787-852-0030
<i>EUROPE</i>		
Dartford, Kent, England	44-1322-293000	44-1322-627200
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Gallarate, Italy	39-0331-776932	39-0331-776831
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<i>ASIA/PACIFIC</i>		
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EX/STAR/PB1199

Colorcon's globally available product line for the pharmaceutical industry includes:

### Complete Film Coating Systems

Opadry®  
Opadry® II  
Opadry® AMB

### Modified Release Products

Sureteric® Aqueous Enteric Coating System  
Surelease® Aqueous Ethylcellulose Dispersion

### Monogramming Inks

Opacode®  
Opacode® WB

### Excipients

Starch 1500® Partially Pregelatinized Maize Starch

### Additional Products

Opaspray® Color Coating Dispersion  
Opatint® Food Coloring System  
Opaseal® Sealant Coating Product  
Opaglos® Tablet Core Sealant Product  
Opalux® Color Coating Product

### FD&C and D&C Aluminium Lakes

### Pigment Blends

